March 1, 2019

Nova Biomedical Corporation
Paul MacDonald
Chief Quality Assurance and Regulatory Affairs Officer
200 Prospect Street
Waltham, MA 02454-9141

Re: K150461
Trade/Device Name: StatStrip Xpress Glucose Hospital Meter System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: PZI
Dated: February 20, 2015
Received: February 23, 2015

Dear Paul MacDonald:

This letter corrects our substantially equivalent letter of May 20, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150461

Device Name
StatStrip Xpress Glucose Hospital Meter System

Indications for Use *(Describe)*

The StatStrip Xpress Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood and neonate heel stick specimens.

The StatStrip Xpress Glucose Hospital Meter System is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings.

The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick.

It is not intended for use with neonate cord blood specimens.

It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

510(K) Owner:	Nova Biomedical Corporation
Registration Number:	1219029
Address:	200 Prospect St. Waltham, MA 02454
Phone:	781-894-0800
Fax Number:	784-891-4806
Contact Person:	Paul W. MacDonald
Date Prepared:	**8 May, 2015**

Proprietary Name: StatStrip Xpress Glucose Hospital Meter System

Common or Usual Name: Blood Glucose Meter

Classification Name: Multiple

Classification Names:	Class No.	Reg. No.	Class
Glucose Oxidase	75CGA	862.1345	II

Product Codes: CGA, Glucose Oxidase, Glucose

Predicate Device: K132121 - StatStrip Glucose Hospital Meter System

Device Description:

Intended Use:

The StatStrip Xpress Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick specimens.

The StatStrip Xpress Glucose Hospital Meter System is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings.

The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick.

It is not intended for use with neonate cord blood specimens.

It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

Summary of the Technological Characteristics:

Hospital Meter

The StatStrip Xpress Glucose Hospital Meter System that is the subject of this submission is identical in form, fit and function, to the device originally cleared in K070960. The StatStrip Xpress Glucose Hospital Meter System is specifically designed to meet the bedside and point-of-care glucose testing needs in today's hospital environment. The system is intended for in vitro diagnostic use by health care professionals for both clinical and point-of-care usage for the quantitative determination of glucose in whole blood. It is intended to provide plasma equivalent results to laboratory methods. The StatStrip Xpress Glucose Hospital Meter System is intended for use in a clinical setting by healthcare professionals as an aid to monitor glucose levels in the management of dysglycemia.

The StatStrip Xpress Glucose Hospital Meter is a hand-held testing device that works in conjunction with the StatStrip Glucose Test Strips. Meter operation is self-prompting using a segmented liquid crystal display (LCD) and icons. Function and data selection is accomplished using 3 push buttons. The handheld meter supports audible alerts and prompts with a built-in beeper. In addition to measuring glucose, the meter also stores up to 400 patient test records. The user can recall and review test results.

A single coin battery powers the device, and is expected to perform up to 600 tests before needing to be replaced. A low battery prompt will appear when it is time to replace the battery. All test data is stored in a non-volatile form to prevent data loss.

Test Strips

The StatStrip Glucose Hospital Meter Test Strips that are the subject of this submission are identical in form, fit, function and packaging, to the glucose test strips originally cleared for use with the system in K070960. The Test Strip is designed with an electrode that measures Glucose levels. Glucose in the blood sample mixes with reagent on the test strip that produces an electric current. The amount of current that is produced depends on how much Glucose is in the blood.

The strip is designed such that when a drop of blood is touched to the end of the strip, the blood is drawn into the reaction space via capillary action. A simple one-step process provides a blood glucose result. Test strips will be sold in cartons of 100 strips (50 strips/vial).

Contents:

Each glucose test strips contain a reaction layer that contains glucose enzyme (Aspergillus sp.) >1.0 IU, mediator >20 µg, and other nonreactive substances.

Function:

StatStrip Glucose Test Strips are intended for quantitative determination of Glucose in fresh whole blood specimens. StatStrip Glucose Test Strips are for use only with the StatStrip Family of Meters.

Storage Conditions:

Store the test strips in the vial between 34-86°F (1-30°C); between 10-90% relative humidity (non-condensing). Ensure that the vial is closed between uses. Once opened the test strips in the vial may be used for 180 days or until the expiration date printed on the label, which ever comes first.

Controls and Linearity Solutions

The StatStrip Control and Linearity Solutions that are intended for use with the system are identical in formulation and packaging, to the Control and Linearity Solutions originally cleared for use with the system in K070960.

Control Solutions

The StatStrip Control Solutions are aqueous solutions that contain no products of human origin. The controls solutions are for use with all of the StatStrip Meters.

Contents

Each vial contains approximately 4mLs of a buffered aqueous control solution containing glucose, β-ketone, preservative, viscosity-adjusting agent and other non-reactive ingredients (dye).

There are three levels of control solutions (Levels 1-3).

StatStrip Glucose Control Solutions are intended to verify the accuracy of the blood Glucose test results.

Storage Conditions

Store the control solution in the vial at room temperature. Ensure that the vial is closed between uses. Once opened the control solution may be used for up to 9 months or until the expiration date printed on the label, which ever comes first.

Linearity Solutions

The StatStrip Glucose Linearity Solutions are aqueous materials with a known concentration of glucose intended to verify performance of the Nova Biomedical Analyzers. Assay values for expected ranges are included on every bottle of linearity standards. If the results obtained are outside the expected range, the system may not be performing correctly.

Contents

Each vial contains 4mLs of a buffered glucose, β-ketone, preservative, viscosity-adjusting agent and other non-reactive ingredients (dye). They contain no products of human origin.

There are five levels of linearity solutions (Levels 1-5).

Function

The Linearity Solution is intended for monitoring the performance (linearity) of the StatStrip Glucose Hospital Meter System.

Storage conditions:

Store the linearity solution in the vial at room temperature (below 86°F/30°C). Ensure that the vial is closed between uses. Once opened the control solution may be used for up to 3 months or until the expiration date printed on the label, whichever comes first.

Summary of Performance Testing:

The results of the performance verification testing confirmed that the StatStrip Xpress Glucose Hospital Meter System is safe and effective for its intended purpose and that the StatStrip Xpress Glucose Hospital Meter System is substantially equivalent to the predicate StatStrip Glucose Hospital Meter System (K132121).

Table 2-1: Comparison of Predicate and Proposed devices

Item	Predicate Device (K132121)	Modified Device
	StatStrip Glucose Hospital Meter System	StatStrip Xpress Glucose Hospital Meter System
Intended Use	The StatStrip Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood and neonate heel stick specimens. The StatStrip Glucose Hospital Meter System is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial samples throughout all hospital and all professional healthcare settings. The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick. It is not intended for use with neonate cord blood specimens. It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.	The StatStrip Xpress Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood and neonate heel stick specimens. The StatStrip Xpress Glucose Hospital Meter System is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial samples throughout all hospital and all professional healthcare settings. The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick. It is not intended for use with neonate cord blood specimens. It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.
Operating Principle	Electrochemical biosensor	Same
Sample type	Capillary whole blood (finger stick), venous whole blood, arterial whole blood, neonate heel stick, and neonate arterial whole blood specimens Venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood samples throughout all hospital and all professional	Same
Sample size	1.2 µL	Same
Sample application	Test strip capillary draw	Same
Measuring range	10-600 mg/dL	Same

Item	Predicate Device (K132121)	Modified Device
	StatStrip Glucose Hospital Meter System	StatStrip Xpress Glucose Hospital Meter System
Hematocrit range	20-65%	Same
Reported output	mg/dL	Same
Time to Result	~ 6 seconds	Same
Calibration	Automatic, no Calibration Code	Same
Test strip active reagent	Glucose Oxidase	Same
Quality Control	3 levels	Same
Linearity	5 levels	Same
Handheld?	Yes	Same
Data storage	1000 patient test results and 200 QC test results	400 test results
Barcode	Yes	No
Power source	Rechargeable 3.7 volt Lithium battery	3v dc Li coin cell battery